

468, filed Jan. 28, 2016 and U.S. patent application Ser. No. 15/009,480, filed Jan. 28, 2016, both of which are continuations of U.S. patent application Ser. No. 14/872,226, filed Oct. 1, 2015, now U.S. Pat. No. 9,295,642, which is a continuation of U.S. patent application Ser. No. 14/624,998, filed Feb. 18, 2015, now U.S. Pat. No. 9,180,100, which is a continuation of U.S. patent application Ser. No. 14/300,580, filed Jun. 10, 2014, now U.S. Pat. No. 8,999,386, prior International Patent Application No. PCT/US2013/054930, filed Aug. 14, 2013 and U.S. Provisional Patent Application Nos. 61/774,783, filed Mar. 8, 2013 and 61/683,513, filed Aug. 15, 2012, are incorporated herein by reference. While the invention has been described with reference to a particularly preferred embodiment, it will be appreciated that modifications can be made without departing from the spirit of the invention. Such modifications are intended to fall within the scope of the appended claims.

The invention claimed is:

1. An extended release racemic methylphenidate chewable tablet, wherein the chewable tablet is a solid dispersion comprising:

- (a) a sustained release, racemic methylphenidate component comprising a water-insoluble, water-permeable, pH-independent barrier coated, racemic methylphenidate-cation exchange resin complex which comprises:
 - (i) a racemic methylphenidate-cation exchange resin complex comprising racemic methylphenidate and a pharmaceutically acceptable cation ion exchange resin, wherein the racemic methylphenidate is bound to the pharmaceutically acceptable cation exchange resin;
 - (ii) a water-insoluble, water-permeable, pH-independent, barrier coating comprising cellulose acetate and a plasticizer; wherein the barrier coating provides a sustained release profile to the racemic methylphenidate as defined in (a); and
- wherein about 50% w/w to about 90% w/w of total racemic methylphenidate in the chewable tablet is provided by the sustained release component; and
- (b) an immediate racemic methylphenidate component comprising racemic methylphenidate-cation exchange resin complex which provides a release of the racemic methylphenidate in less than about 30 minutes as determined in an in vitro dissolution assay, wherein the methylphenidate-cation exchange resin complex comprises racemic methylphenidate bound to a pharmaceutically acceptable cation exchange resin;

wherein the chewable tablet is capable of being divided and providing tablet portions which retain a therapeutically effective extended release profile, and a pharmacokinetic profile in which the racemic methylphenidate has at least one of: a geometric mean for area under the curve (AUC)_{0-∞} of about 110 ng-hr/mL to about 140 ng-hr/mL or a geometric mean C_{max} of about 10 ng/mL to about 15 ng/mL, under fasted conditions in adults following a single oral administration of the chewable tablet which has a total amount of racemic methylphenidate which is the equivalent of 40 mg racemic methylphenidate HCl.

2. The extended release racemic methylphenidate chewable tablet according to claim 1, wherein the plasticizer is selected from propylene glycol, polyethylene glycol, dibutyl sebacate, propylene glycol, polyethylene glycol, polyvinyl alcohol, triethyl citrate, acetyl triethyl citrate, acetyl tributyl citrate, tributyl citrate, triacetin, 2-pyrrolidone, or mixtures thereof.

3. The extended release racemic methylphenidate chewable tablet according to claim 1, wherein the plasticizer comprises triethyl citrate.

4. The extended release racemic methylphenidate chewable tablet according to claim 1, wherein the plasticizer comprises polyethylene glycol.

5. The extended release racemic methylphenidate chewable tablet according to claim 1, wherein the barrier coating is applied as a solvent based suspension.

6. The extended release racemic methylphenidate chewable tablet according to claim 1, wherein the barrier coating is cured.

7. The extended release racemic methylphenidate chewable tablet according to claim 1, wherein the water-insoluble, water-permeable, pH-independent polymer is present in the barrier coat an amount of about 70% to about 90% w/w, based on the weight of the final barrier coating layer.

8. The extended release racemic methylphenidate chewable tablet according to claim 1, wherein the barrier coating is about 15% by weight to about 65% by weight of the methylphenidate-cation ion exchange resin complex defined in (i) as determined prior to the racemic methylphenidate-cation exchange resin complex being coated with the barrier coating of (ii), wherein the racemic methylphenidate-cation exchange resin is optionally in a matrix which further comprises at least one polymer or copolymer.

9. The extended release racemic methylphenidate chewable tablet according to claim 1, wherein the barrier coat is present in an amount of about 20% w/w to about 50% w/w % based on the weight of the racemic methylphenidate-cation exchange resin complex defined in (i) as determined prior to the racemic methylphenidate-cation exchange resin complex being coated with the barrier coating of (ii), wherein the racemic methylphenidate-cation exchange resin is optionally in a matrix which further comprises at least one polymer or copolymer.

10. The extended release racemic methylphenidate chewable tablet according to claim 1, wherein the barrier coat is present in an amount of about 20% w/w to about 35% w/w % based on the weight of the racemic methylphenidate-cation exchange resin complex defined in (i) as determined prior to the racemic methylphenidate-cation exchange resin complex being coated with the barrier coating of (ii), wherein the racemic methylphenidate-cation exchange resin is optionally in a matrix which further comprises at least one polymer or copolymer.

11. The extended release racemic methylphenidate chewable tablet according to claim 10, wherein the immediate release component comprises about 20% w/w to about 40% w/w of the total racemic methylphenidate in the chewable tablet.

12. The extended release racemic methylphenidate chewable tablet according to claim 1, wherein the barrier coated methylphenidate-cation exchange resin complex as defined in (ii) are particulates having a mean particle size in the range of about 100 microns to about 450 microns.

13. The extended release racemic methylphenidate chewable tablet according to claim 12, wherein the barrier coated methylphenidate-cation exchange resin complex as defined in (ii) are particulates having a mean particle size in the range of about 150 microns to about 300 microns.

14. The extended release racemic methylphenidate chewable tablet according to claim 1, wherein the sustained release methylphenidate component provides about 60% w/w to about 80% w/w of the methylphenidate in the chewable tablet, based on the total amount of methylphenidate in the chewable tablet.